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भारतीय मानक

हृदयवाहिका शल्यक्रिया उपकरण — पौट्स स्मिथ नमूने पर आधारित कोण वाली कैंची – विशिष्टि

(पहला पुनरीक्षण)

Indian Standard

CARDIOVASCULAR SURGERY INSTRUMENTS — ANGLED SCISSORS, POTTS SMITH PATTERN — SPECIFICATION

(First Revision)

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FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Thoracic and Cardiovascular Surgery Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first issued in 1977 and covered the requirements for Pott's Smith Pattern, angled on side scissors used in cardiovascular surgery. This has been revised so as to include the Potts Smith pattern, angled on flat scissors, which were earlier covered in IS 8550: 1977 "Scissors, angled on flat, Potts Smith Pattern" thus merging these two standards. Besides, in this revision, tolerances on various dimensions have been modified, the requirements for surface condition and finish including passivation have been incorporatatory and a recommendatory sampling plan has been added.

In view of the above merger, IS 8550: 1977 stands withdrawn.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS 2:1960 'Rules for rounding off numerical values (revised)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

CARDIOVASCULAR SURGERY INSTRUMENTS — ANGLED SCISSORS, POTT'S SMITH PATTERN — SPECIFICATION

(First Revision)

1 SCOPE

1.1 This standard prescribes dimensional and other requirements for Potts Smith pattern, angled scissors used in cardiovascular surgery.

2 REFERENCES

2.1 The Indian Standards listed below are necessary adjuncts to this standard:

IS No.	Title
1501 (Part 1): 1984	Method for Vickers hardness test for metallic materials:
(1411.)	Part 1 HV 5 to 100 (second revision)
3642	Specification for surgical in-
(Part 1): 1990	struments: Part 1 Non-cutting,
,	articulated type instruments
	(second revision)
4905: 1968	Methods for random sampling
6603:1972	Specification for stainless steel bars and flats
7531 : 1990	Methods of test for corrosion resistance of stainless steel surgical instruments (first revision)

3 MATERIAL

3.1 The scissors shall be made of stainless steel conforming to Designation 40Cr13 of IS 6603: 1972.

4 TYPES, SHAPES AND DIMENSIONS

- **4.1** The angled scissors shall be of the following two types:
 - a) Angled on side (see Fig. 1)
 - b) Angled on flat (see Fig. 2)
- **4.2** The shape and dimensions of the scissors shall be as shown in Fig. 1 and 2.

4.3 Tolerances

The tolerances on linear and angular dimensions shall be as specified in IS 3642 (Part 1): 1990.

4.3.1 The two halves of the scissors shall, however, not differ at any identical dimension and shall match with each other perfectly.

4.4 Joints

The joint shall be screw type (lay on) joint conforming to IS 3642 (Part 1): 1990.

4.5 Finger Loops

The finger loops shall conform to size No. 2 of 1S 3642 (Part 1): 1990.

5 WORKMANSHIP

- 5.1 All edges shall be rounded, except the cutting edges, which shall be sharp and uniform. The cutting edges shall not have nicks, jags and wavyness, when examined under a magnification of \times 10.
- 5.2 The cutting edges shall coincide along their lengths and tips when the scissors are fully closed.
- 5.3 The blades of the scissors shall fully open and close with two fingers, without stiffness and shall have a slight cross over action to give a continuous pinch.

6 SURFACE CONDITION AND FINISH

6.1 General

All surfaces shall be free from pores, crevices, pits, burrs, cracks, grinding marks and other defects. The scissors shall be supplied free from residual scale, acid, grease, grinding and polishing materials. Compliance with these requirements shall be checked by visual inspection.

6.2 Surface Finish

The scissors shall have a mirror polish or reflection reducing finish, for example, satin finish; matt black finish.

NOTES

- 1 The satin finish should be achieved using an appropriate procedure, for example grinding, brushing electro-polishing and, in addition, satin finishing (glass beading or satin brushing). The finish should be uniform and smooth, and it should reduce glare.
- 2 Instruments of mirror finish should be adequately ground to remove all surface imperfections and polished to remove grinding marks in order to achieve a mirror finish. This should be achieved using an appropriate procedure, for example polishing brushing, electropolishing and mirror buffing.

6.3 Passivation and Final Treatment

The scissors shall be treated by a suitable passivation process, for example by electropolishing or by treatment with 10 percent (v/v) Nitric acid solution for not less than 30 minutes at a temperature not less than 10°C and not exceeding 60°C. The scissors shall then be rinsed in water and dried in hot air.

7 HEAT TREATMENT

- 7.1 The vickers hardness of the finished scissors excluding screw shall be with in a range of 550 to 650 HV when tested in accordance with IS 1501 (Part 1): 1984.
- **7.2** Mating surfaces of the same scissors such as opposite jaws and shanks, shall not vary in hardness by more than 40 HV.

8 SAMPLING

8.1 The scale of sampling and criteria for conformity of the scissors to the requirements of this specification shall be as agreed to between the purchaser and the supplier. A recommended sampling plan is given in Annex A.

9 TESTS

9.1 Corrosion Resistance Test

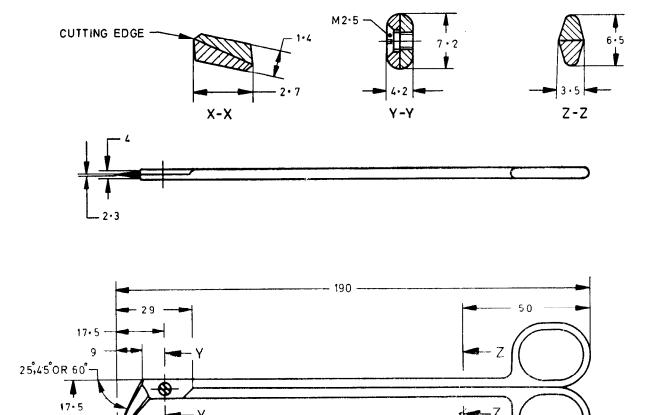
The scissors shall be tested for corrosion resistance in accordance with IS 7531: 1990. They shall pass the test.

9.2 Performance

The scissors shall be made to cut 0.5 mm thick chamois leather or kid leather 100 times along two-thirds of the blade without lateral pressure. The scissors shall cut the leather cleanly without tearing or sticking and shall not show any sign of damage during or after the test. The scissors shall continue to function in the original manner after the test.

10 MARKING AND PACKING

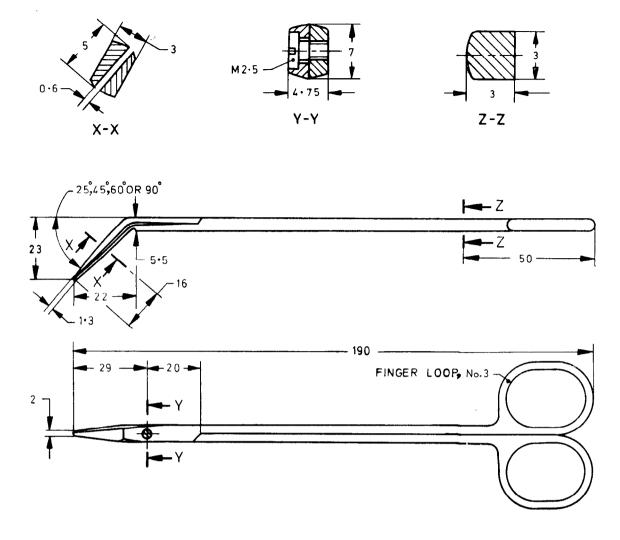
- 10.1 The scissors shall be legibly and indelibly marked with the indication of the source of manufacture, the words stainless steel or letters 'SS' to indicate that the scissor is made of stainless steel.
- 10.2 Each scissor shall be wrapped in a suitable cushioning material like folded tissue paper. It



All dimensions in millimetres.

FINGER LOOP, No. 2

Fig. 1 Scissors, Angled on Side, Pott's Smith Pattern



All dimensions in millimetres.

FIG. 2 SCISSORS, ANGLED ON FLAT, POTTS SMITH PATTERN

shall then be put in a polyethylene bag or wrapped in wax paper. The scissor shall thereafter be packed in cartons in accordance with the current trade practices.

10.2.1 Alternatively, the instrument may be

packed as agreed to between the purchaser and the supplier.

10.3 The package shall be marked with the name and shape of the instrument; identification of the source of manufacture, the words 'stainless steel' and the country of manufacture.

ANNEX A

(Clause 8.1)

SAMPLING OF SCISSORS, ANGLED, POTTS SMITH PATTERN

A-1 LOT

In any consignment, all the instruments of the same type and shape, produced from the identical material under similar conditions and having the same surface finish shall constitute a lot.

A-2 The number of instruments to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

Table 1 Scale of Sampling (Clauses A-2, A-3.1 and A-3.2)

Lot Size	Sample Size	Sub-Sample Size
(1)	(2)	(3)
Up to 15	2	1
16 to 50	3	1
51 to 150	5	2
151 and above	8	3

A-2.1 These instruments shall be selected from the lot at random and in order to ensure random-

ness of selection, procedures given in IS 4905: 1968 may be followed.

A-3 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

A-3.1 All the instruments selected according to col 1 and 2 of Table 1 shall be examined for shape and dimensions, workmanship and surface condition (visual), and tested for performance, An instrument in the sample failing to meet any of these requirements shall be considered as defective. The lot shall be considered as conforming to these requirements, if no defective is found in the sample.

A-3.2 The lot having been found satisfactory according to A-3.1 shall be further tested for other requirements. For this purpose, a subsample of size given in col 3 of Table 1 shall be taken. These instruments in the sub-sample may be selected from those already examined according to A-3.1. Each instrument in the sub-sample shall be subjected to hardness, and corrosion resistance test. The lot shall be declared as conforming to the requirements of the specification if none of the instruments in the sub-sample fails in any of these tests.

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